Standar Nasional Indonesia

SNI EN 14126:2003
(Ditetapkan oleh BSN tahun 2020)

Pakaian pelindung – Persyaratan kinerja dan metode uji terhadap agen infeksius

Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

(EN 14126:2003, IDT, Eng)

SNI ini merupakan adopsi identik dari EN 14126:2003 dan telah mendapat izin adopsi dari CEN, Rue de la Science 23 B – 1040 Brussel, Belgium

This national standard is the identical implementation of EN 14126:2003 and is adopted with permission of CEN, Rue de la Science 23 B – 1040 Brussels, Belgium

ICS 13.340.10

BADAN STANDARDISASI NASIONAL

BSN
Email: dokinfo@bsn.go.id
www.bsn.go.id

Diterbitkan di Jakarta

Daftar isi

Daftar isi i
Prakata ii
1 Scope 1
2 Normative reference 1
3 Term and definition 2
4 Requirements 3
5 Marking 5
6 Information supplied by the manufacturer 6
Annex A (normative) Test method for resistance to wet bacterial barrier penetration 7
Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives 17
Bibliografi 18

Prakata

Standar Nasional Indonesia (SNI) EN 14126:2003, dengan judul *Pakaian pelindung – Persyaratan kinerja dan metode uji terhadap agen infeksius (EN 14126:2003, IDT, Eng)*, merupakan hasil adopsi identik dari standar EN 14126:2003 *Protective clothing - Performance requirements and tests methods for protective clothing against infective agents*, dengan metode republikasi *reprint*, yang ditetapkan oleh BSN pada tahun 2020.

Standar ini disusun oleh Komite Teknis 13-09 Biosafety and Biosecurity dengan Badan Standardisasi Nasional (BSN) sebagai sekretariat Komite Teknis. Standar ini telah dibahas dalam rapat-rapat teknis, dan terakhir disepakati dalam rapat konsensus di Jakarta pada tanggal 17 April 2020 yang dihadiri oleh para pemangku kepentingan (*stakeholder*) terkait, yaitu perwakilan dari produsen, konsumen, pakar dan pemerintah, serta perwakilan dari lembaga penguji, asosiasi, perguruan tinggi, pakar serta instansi terkait.

Standar ini telah melalui tahap jajak pendapat pada tanggal 11 Mei 2020 sampai dengan 30 Mei 2020 dengan hasil akhir disetujui menjadi SNI.

Dalam standar ini digunakan kosa kata yang mempunyai maksud tertentu, yaitu:

- "harus" yang artinya disyaratkan.
- "sebaiknya" yang artinya direkomendasikan.

Perlu diperhatikan bahwa kemungkinan beberapa unsur dari dokumen standar ini dapat berupa hak paten. Badan Standardisasi Nasional tidak bertanggungjawab untuk pengidentifikasian salah satu atau seluruh hak paten yang ada.

Pendahuluan

Protective clothing against infective agents has two main functions:

- to prevent infective agents from reaching the (possibly injured) skin;
- to prevent the spreading of infective agents to other people and other situations, e.g. eating or drinking, when the person has taken his protective clothing off.

In many work situations, e.g. microbiological laboratories, biotechnological production, etc. the infective agents can be contained and the risk of exposure is limited to the occurrence of an accident. In these situations the agents, to which the worker can be exposed, are usually well known. In other types of work, the organisms can not be contained, exposing the worker continuously to the risk of infection by biological agents. This happens e.g. in sewage work, waste treatment, caring for animals infected with zoonotic agents, emergency clean-up, treatment of hospital risk waste etc. In these situations, the agents the workers are exposed to, may not be known, although possible risks can be assessed.

Micro-organisms are a very heterogeneous group of organisms as to their size, shape, living conditions, infective dose, survival abilities and many other parameters. Their size alone can vary from 30 nm (poliovirus) to 5 µm to 10 µm (bacteria) and even larger (most fungi). A hazard classification of micro-organisms can be found in European Directive 2000/54/EEC (on the protection of workers from the risk related to exposure to biological agents at work).

Due to the heterogeneity of micro-organisms, it is not possible to define performance criteria on the basis of risk groups, nor on the type of micro-organism. Also it may not be possible to define exactly the organisms the worker is exposed to. Hence the test methods specified in this standard focus on the medium containing the micro-organism, such as a liquid, an aerosol or a solid dust particle. A risk analysis should determine which ones of these risks are present in a given situation.

Pakaian pelindung – Persyaratan kinerja dan metode uji terhadap agen infeksius

1 Scope

This standard specifies requirements and test methods for re-usable and limited use protective clothing providing protection against infective agents.

Clothing worn by surgical teams or drapes laid on patients to prevent cross-contamination during surgical interventions are not covered by the scope of this standard.

2 Normative reference

This standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 340 [1)], *Protective clothing — General requirements*.

EN 465 [1)], *Protective clothing — Protection against liquid chemicals – Performance requirements for chemical protective clothing with spray-tight connections between different parts of the clothing (Type 4 Equipment).*

EN 466 [1)], *Protective clothing — Protection against liquid chemicals – Performance requirements for chemical protective clothing with liquid-tight connections between different parts of the clothing (Type 3 Equipment).*

EN 467 [1)], *Protective clothing — Protection against liquid chemicals – Performance requirements for garments providing protection to parts of the body*.

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods*.

EN 943-1, *Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles — Part 1: Performance requirements for ventilated and non-ventilated "gas-tight" (Type 1) and "non-gas-tight" (Type 2) chemical protective suits.*

EN 943-2, *Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles — Part 2: Performance requirements for "gas-tight" (Type 1) chemical protective suits for emergency teams (ET).*

prEN 13034, *Protective clothing for use against liquid chemicals — Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (type 6 equipment).*

[1)] revision currently in progress

EN 13795-1, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical stuff and equipment - Part 1: General requirements for manufacturers, processors and products.*

prEN ISO 13982-1, *Protective clothing for use against solid particulate chemicals — Part 1: Performance requirements for chemical protective clothing providing protection to the full body against solid particulate chemicals (type 5 clothing) (ISO/DIS 13982-1:2000).*

prEN 14325, *Protective clothing against chemicals — Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages.*

ISO 139, *Textiles; Standard atmospheres for conditioning and testing.*

prCEN ISO/TR 11610, *Protective clothing — Glossary of terms and definitions. (ISO/DTR 11610:2002)*

ISO/FDIS 16603, *Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood.*

ISO/FDIS 16604, *Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X-174 Bacteriophage.*

ISO/DIS 22611, *Clothing for protection against infectious agents — Test method for resistance to penetration by biologically contaminated aerosols.*

ISO/DIS 22612, *Clothing for protection against infectious agents — Test method for resistance to penetration by biologically contaminant dust through protective clothing materials.*

3 Term and definition

For the purposes of this standard, the terms and definitions of prCEN ISO/TR 11610:2003 and the following terms and definitions apply.

3.1
infective agents
micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity [2)]

3.2
protective clothing against biological agents
combined assembly of garments, intended to afford protection to the skin against exposure to or contact with infective agents

3.3
protective clothing material against infective agents
any material or combination of materials used in an item of protective clothing for the purpose of isolating parts of the body from direct contact with an infective agent

---

[2)] European Directive 90/679/EEC on the protection of workers from the risk related to exposure to biological agents at work.

3.4
protective suit against infective agents
suit protecting against infective agents which can be hazardous to the health. A suit may have various types of additional protection such as a hood or helmet, boots and gloves

4 Requirements

4.1 Materials requirements

4.1.1 General

If the care instructions indicate that the clothing can be cleaned and reprocessed at least five times, protective clothing materials shall be submitted to five cleaning and reprocessing cycles according to the manufacturer's care instructions before testing.

If the care instructions specify a lower number of cleaning/reprocessing cycles, then materials shall be submitted to the number of cleaning/reprocessing cycles indicated.

Unless otherwise stated in the relevant test procedure, the specimens shall be conditioned for at least 24 h in an atmosphere of (20 ± 2) °C and (65 ± 5) % relative humidity before testing. Tests shall be carried out in the same atmosphere or within 5 min of removing the sample from the conditioning atmosphere.

4.1.2 Mechanical and flammability requirements

The materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.

4.1.3 Chemical requirements

If protection against chemicals is claimed, the materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.

4.1.4 Performance requirements against penetration by infective agents

4.1.4.1 Resistance to penetration by contaminated liquids under hydrostatic pressure

When tested in accordance with ISO/FDIS 16603 and ISO/FDIS 16604 the material shall be classified according to the levels of performance given in Table 1, as obtained in the bacteriophage test (ISO/FDIS 16604).

NOTE The synthetic blood test (ISO/FDIS 16603) is used for screening purposes, i.e. to predict the level where a strikethrough can be expected when performing the bacteriophage test (ISO/FDIS 16604)

Table 1 — Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (ISO/FDIS 16604)

Class	Hydrostatic pressure at which the material passes the test
6	20 kPa
5	14 kPa
4	7 kPa
3	3,5 kPa
2	1,75 kPa
1	0 kPa[a]
[a] this means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell	

4.1.4.2 Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.

When tested in accordance with Annex A the material shall be classified according to the levels of performance given in Table 2.

Table 2 — Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids

Class	Breaktrhrough time, *t* min
6	$t > 75$
5	$60 < t \leq 75$
4	$45 < t \leq 60$
3	$30 < t \leq 45$
2	$15 < t \leq 30$
1	≤ 15 min

4.1.4.3 Resistance to penetration by contaminated liquid aerosols

When tested in accordance with ISO/DIS 22611 the material shall be classified according to the levels of performance given in Table 3.

Table 3 — Classification of resistance to penetration by contaminated liquid aerosols

Class	Penetration ratio (log)
3	log > 5
2	3 < log ≤ 5
1	1 < log ≤ 3

4.1.4.4 Resistance to penetration by contaminated solid particles.

When tested in accordance with ISO/DIS 22612 the material shall be classified according to the levels of performance given in Table 4.

Table 4 — Classification of resistance to penetration by contaminated solid particles

Class	Penetration (log cfu)
3	≤ 1
2	1 < log cfu ≤ 2
1	2 < log cfu ≤ 3

4.2 Performance requirements for seams, joins and assemblages

Seams, joins and assemblages of protective clothing against infective agents shall fulfil the requirements specified in the relevant clauses of prEN 14325 Seam strength shall be classified according to 5.5 of prEN 14325:2001.

4.3 Whole suit requirements

Protective clothing against infective agents shall fulfil the relevant requirements of EN 340 and the whole suit requirements specified in the relevant standard for chemical protective clothing (see Table 5).

The materials and design used shall not cause skin irritation nor have any adverse effect to health.

NOTE The suit should be as light and as flexible as possible in order to ensure the comfort of the wearer, not to hinder movements and still provide at the same time effective protection.

Table 5 — Types of protective clothing against infective agents

Type of clothing	Relevant standard
Type 1a, 1b, 1c, 2	EN 943-1 (EN 943-2 for ET suits)
Type 3	EN 466
Type 4	EN 465
Type 5	prEN ISO 13982-1
Type 6	prEN 13034
Partial body protection	EN 467

5 Marking

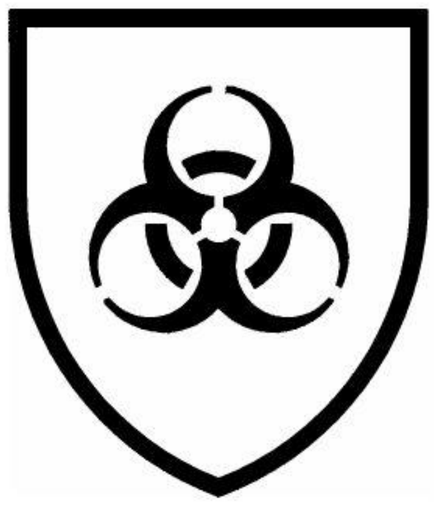
The clothing shall be marked in accordance with the applicable requirements of the relevant standard for chemical protective clothing.

The marking of protective clothing against infective agents shall contain the following additional information:

a) the number of this European Standard;

b) the type of protective clothing, as specified in Table 5, with the suffix “-B”, e.g. type 3-B;

c) the pictogram “protection against biological hazard”



6 Information supplied by the manufacturer

The information for the user shall be worded clearly and unambiguously and be understandable by a trained person.

The information for the user of protective clothing against infective agents shall contain all the information required by EN 340 and by the relevant standard for that specific type of chemical protective clothing. In addition it shall contain the following information:

a) the number of this standard;

b) the type designation, e.g. type 3-B;

c) the biological agents against which the protective clothing has been tested. This information shall be expressed as performance levels, as specified in 4.1.4.1 to 4.1.4.4 for the relevant types of biological challenge;

d) all other relevant information on performance levels, preferably as a Table;

e) the information necessary for trained persons about:

- application and limitations of use (temperature range, etc.)
- if relevant, checks to be carried out by the wearer before use
- fitting and adjustments, and any accessories needed to provide the claimed level of protection;
- use;
- maintenance, cleaning and disinfection;
- storage;
- if relevant, a warning against problems likely to be encountered;
- if relevant, illustrations, part numbers and marking of spare parts, etc.
- disposal after use.

Annex A
(normative)
Test method for resistance to wet bacterial barrier penetration

A.1 Principle of test

NOTE This annex is included in EN 14126 as a temporary provision. It will be superseded by EN ISO 22610 as soon as this international standard will become publicly available

This Annex describes a test method, with the associated equipment, to determine a material's resistance to penetration of bacteria in a liquid.

A test specimen is put on a lidless agar plate on a rotating disk. On top of the test specimen, a piece of donor material and a piece of approximately 10 m thick HD polyethylene film of corresponding size is placed and materials are fixed using a double steel ring.

An abrasion resistant finger is placed on top of the donor material to exert a specified force on the donor and test specimen to bring them into contact with the agar. The finger is applied to the material by a pivoted lever moved by an excenter cam in such a way that it moves over the entire surface of the plate within 15 minutes. The assemblage of materials is stretched by the weight of the steel ring so that only a small area of the test specimen is brought into contact with the agar surface at a time. Due to the combined effect of rubbing and liquid migration bacteria may spread from the donor material through the test specimen down to the agar surface.

After 15 minutes of testing, the agar plate is replaced and the test repeated. Within five periods of 15 minutes each, tests are performed with the same pair of donor material and test specimen. In that way the test allows for an estimation of the penetration over time.

Finally the bacterial contamination on the test specimen is estimated using the same technique.

The agar plates are incubated to visualise the bacterial colonies, which are then enumerated.

The results are processed in accumulated form to characterize the barrier capability and penetration kinetics of the material.

NOTE This test method may be calibrated using a reference material with an EPP characteristic (see A.6) in the range of 3,5 to 4,0, e.g. a 277g/m^2 polyester fabric with a fluorocarbon finish, washed three times. The reference material should be packed in a sterilizer bag that complies with EN 868-1 (Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods) and sterilized with steam at 121 °C.

A.2 Terms and definitions

The following terms and definitions apply:

A.2.1
agar plate
Petri dish containing sterile agar nutrient medium

A.2.2
carrier material
material used to prepare the donor.

A.2.3
covering material
material used for covering a person, equipment or certain surfaces to prevent the skin bacteria from the person and/or bacteria from other non-sterile surfaces from reaching injured skin (see also EN 13795-1)

A.2.4
donor
carrier material that has been contaminated with a known number of viable cells of a defined strain of Staphylococcus aureus

A.2.5
finger
part of the apparatus for testing resistance to wet bacterial penetration, used to bring donor and test specimen into contact with the surface of an agar plate at one spot

A.2.6
Petri dish
receptacle used to prepare agar plates

A.2.7
test specimen
a piece of covering material for which the resistance to bacterial penetration is going to be determined

A.3 Equipment

A.3.1 Apparatus[3]

A.3.1.1 Turntable

The turntable consists of three parts:

- the motor compartment;
- the agar plate holder;
- the finger holder arm.

The motor compartment contains an electric motor, electric switches and transmission to two outgoing spindles, one for the agar plate holder and one for an excenter operating the finger holder arm. The rotation of the motor spindle is transmitted to the outgoing spindles by means of gear wheels and gear belts in two steps both 11:36 and arranged so that plate holder rotates with (60 ±1) min^{-1} and the excenter with 5,60 min^{-1}. A main electric switch breaks the power supply to the apparatus whereas a clock switch (tolerance 15 min ± 5 s) allows the test to be carried out for a predetermined time.

[3] The equipment can be purchased from e. g. Schütt Labortechnik, Rudolf-Wissel-Straße 11, D-37079 Göttingen, Germany. This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN/TC 162 of the product named. Equivalent products may be used if they can be shown to lead to the same results.

The agar plate holder is mounted on the outgoing plate holder spindle. It has a recess on its top surface that has the same diameter as the agar plate to be used in the test.

The finger holder arm is mounted in a rotatable pivot protruding from the top surface of the motor compartment in such way that it is level when the finger at its end rests on the agar dish surface. The length of the arm is 462 mm and it is carried in the pivot in a ball bearing at a distance of (256 ±0,5) mm from the centre of the finger.

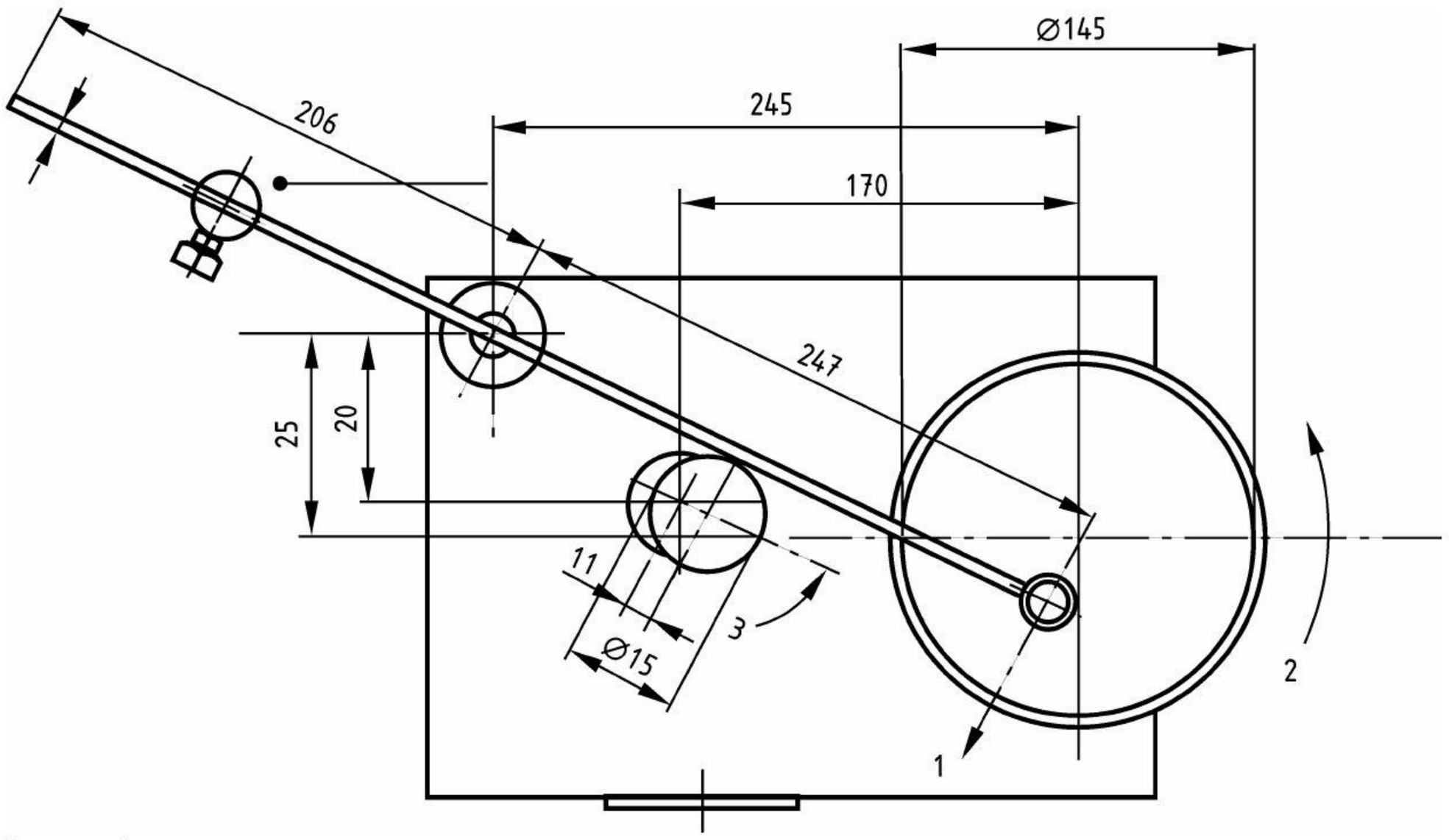
The arm carries a weight of (250 ±0,5) g that may be slid along it to adjust the downward force from the finger to the agar. A loop is attached to the upper edge of the arm at the centre of the finger. It makes it possible to attach a dynamometer when adjusting the downward force. The arm has, at its end, a shaft pointing towards the agar plate holder. It serves the purpose to hold a finger such that it can be removed for disinfection and then fitted again.

The finger shall be made from polished stainless steel polished to R_a = 0,2 µm. The end of the finger being in contact with the test materials shall be semi-spherical with a radius of 11 mm. The finger has a hole in its top surface so that it can be fitted to the shaft on the holder arm. The finger is removable and shall be disinfected between tests.

A force of (3 ± 0,02) N exerted by the finger on the materials is measured by e. g. a dynamometer attached to the lever or by a balance placed on the turntable.

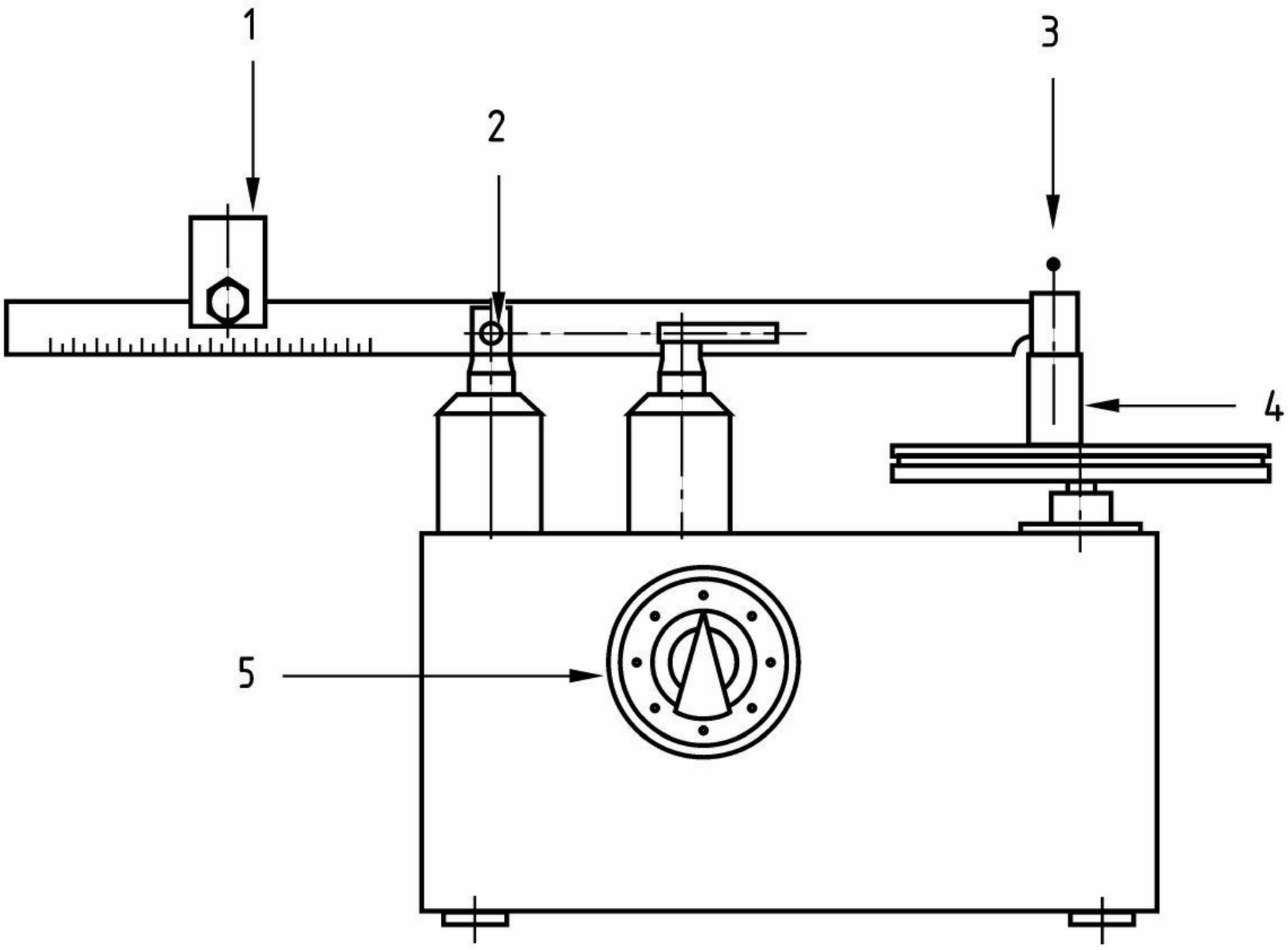
A.3.1.2 Steel ring (figure A3 and A.4)

A double steel ring weighing (800 ±1) g is used to fasten the test material and the donor. The inner diameter is large enough to let the agar plate holder pass through it so that the ring can hang freely outside it.



Legend
1 Spring force 1N
2 rotating velocity 60 min^{-1}

Figure 1 — Apparatus (top view)



Legend

1 Weight
2 Ball bearings
3 Dynamometer attachment point
4 Stainless steel finger R = 11 mm
5 Timer

Figure 2 — Apparatus (front view)

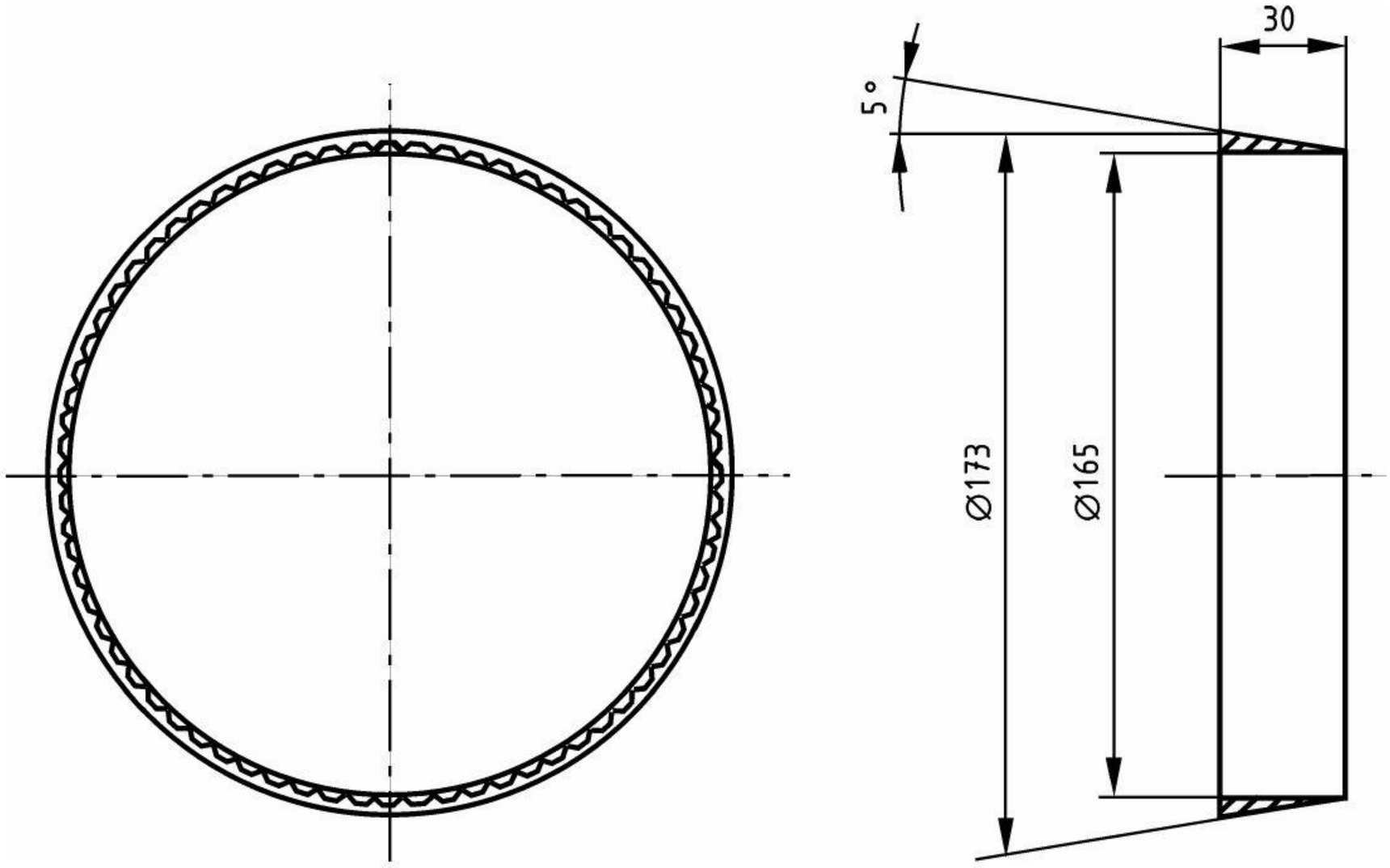


Figure 3 — Inner ring

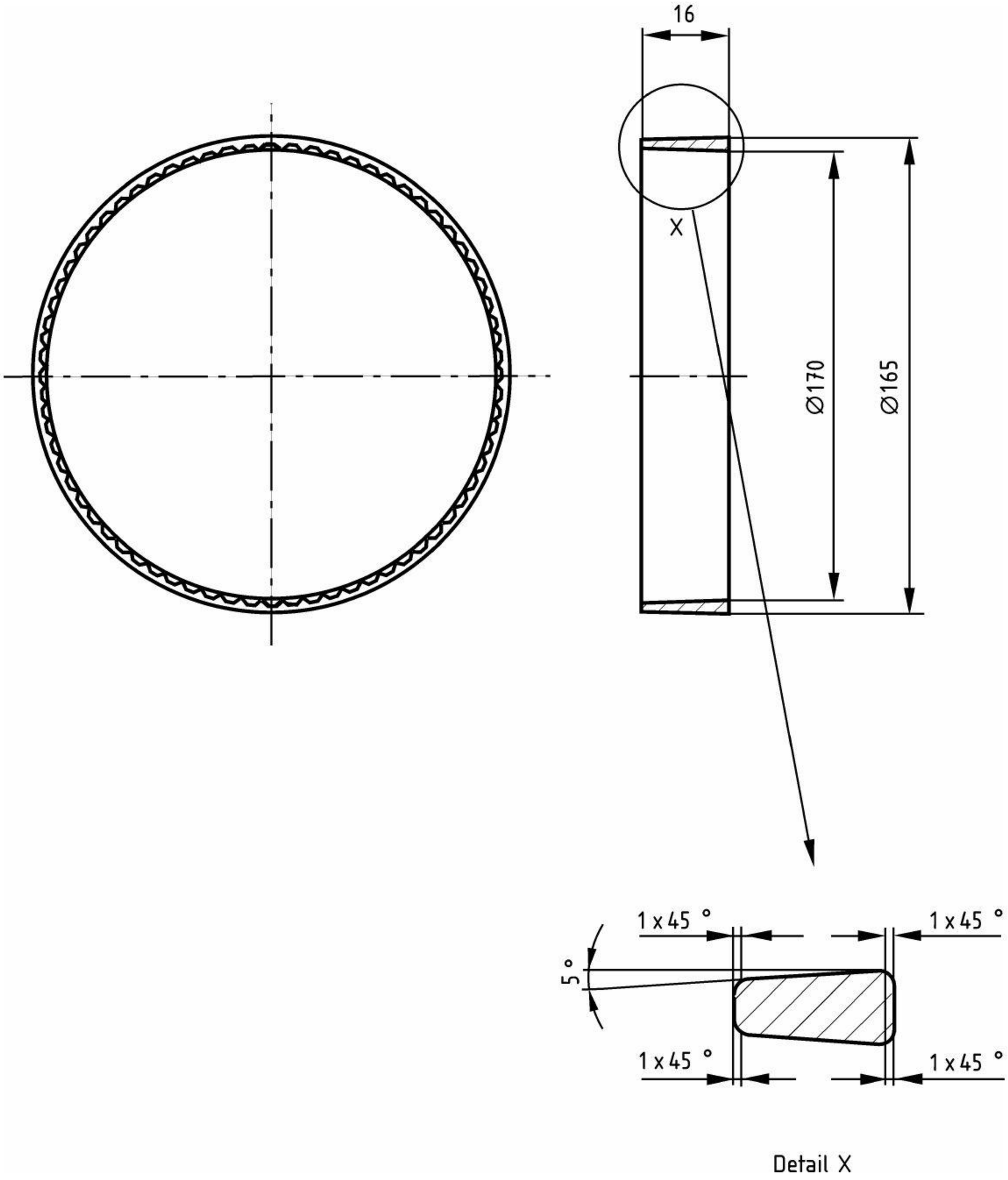


Figure 4 — Outer ring

A.3.2 Sets of 6 agar plates

The set of 6 Petri dishes, 14 cm diameter, is filled with nutrient agar, see A.4, to (3 0,2) mm from the brim. The agar plates shall be prepared the day before the test is performed and be stored over water so that the weight loss is minimized.

Let the plates dry for 20 minutes without lid in a clean bench. Visible fluid (condensate) on the agar surface shall not be present. The height of Petri dishes is not industrially standardized so different suppliers' dishes may have different heights. Therefore the weight or volume of agar that gives the above distance shall be determined. Volumetric or gravimetric methods shall then be used when pouring the agar into the dishes. To monitor the distance agar to brim, put e. g.a razor blade on the center of the agar surface and a steel ruler standing on the dish brim across the dish. Then determine the distance between the ruler and the blade using wire

gauges or a dial indicator. This distance shall be determined for each batch of plates and be noted in the test report.

A.3.3 Carrier material [4]

The carrier material shall be a wettable, solvent cast polyurethane film on paper carrier, with following characteristics :

- thickness: 30 µm
- elongation at maximum load:
- (350 ± 50) % in the machine direction
- (400 ± 75) % in the cross direction

NOTE The PU side of the laminate should be contaminated with the test strain.

Cut pieces of 25 cm x 25 cm from the carrier. Put each piece between sheets of cardboard, and then in a sterilizer bag. Sterilize by steam.

A.3.4 Staphylococcus aureus suspension

S. aureus strain, ATCC 29213, is cultured 18 to 24 h at (36 ± 1) °C on tryptic soy agar.

From this, 2 or 3 colonies are suspended in 3 ml tryptic soy broth, see A.4, and cultured 18 to 24 h at (36 ± 1)°C. The broth is diluted with peptone water, see A.4, in 1:10 steps to yield a dilution to $1x10^4$- $4x10^4$ CFU/ml.

A viable count is performed on the final suspension.

A.3.5 Preparation of donor

Open a sterilizer bag and extract the polyurethane film. Place the carrier material on a clean tray, wettable PU side up.

For ease of handling fix the carrier to the tray using double sided adhesive tape in the corners. An area corresponding to the lid of the agar plate is marked on the carrier material.

1,0 ml of the *S. aureus* suspension is distributed over this area of the carrier material. The donor is then dried at 56 °C for approx 30 min. The *S. aureus* suspension is further spread on the polymer film during the drying using a disinfected glass spreader to ensure an even spread.

The donor shall be used the same day as it is prepared.

---

[4] The material can be purchased from e. g. Schütt Labortechnik, Rudolf-Wissel-Straße 11, D-37079 Göttingen, Germany. This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN/TC 162 of the product named. Equivalent products may be used if they can be shown to lead to the same results.

A.3.6 Covering film [5]

Five pieces, 25 cm x 25 cm, of approx 10 µ HD polyethylene film with a density of (950 ± 2) kg/m^3 and a MFR (190°C, 5kg) of 0,27 g/10 min.

A.3.7 Test specimens

Five pieces 25 cm x 25 cm or with a diameter of 25 cm shall be randomly cut under aseptic conditions from the material to be tested.

When applicable, prior to testing, the test specimens are packed and sterilized, using the same packaging and sterilizing methods as those recommended by the manufacturer for the final product.

A.4 Nutrient media

A.4.1 Tryptic soy agar

- Tryptone 15 g
- Papaic digest of soybean meal 5 g
- Sodium chloride 5 g
- Agar 17 g
- Dest. water 1000 ml

Suspend dry ingredients in water and heat while swirling to dissolve and mix. Sterilize at 121°C for 15 minutes, swirl thoroughly and dispense.

A.4.2 Tryptic soy broth

- Tryptone 17 g
- Papaic digest soybean meal 3 g
- Dextrose 2,5 g
- Sodium chloride 5 g
- Dipotassium phosphate 2,5 g
- Dest. water 1000 ml

A.4.3 Peptone water

- Peptone 10 g
- Sodium chloride 5 g
- Polysorbate 80 1 g
- Dest. water 1000 ml

[5)] The material can be purchased from e. g. Schütt Labortechnik, Rudolf-Wissel-Straße 11, D-37079 Göttingen,Germany. This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN/TC 162 of the product named. Equivalent products may be used if they can be shown to lead to the same results.

A.4.4 Nutrient agar

- Beef extract 3 g
- Peptone 5 g
- Sodium chloride 8 g
- Agar 17 g
- Dest. Water 1000 ml

Preparation, see A.4.1. Use plates day after preparation.

A.5 Test method

A.5.1 Conditioning

If required, condition the test specimens according to ISO 139 Textiles -- Standard atmospheres for conditioning and testing.

Otherwise, conditioning and testing may be carried out at normal room temperature. The method for conditioning shall be disclosed in the test report.

A.5.2 Calibration of apparatus

The material under test shall only be in contact with the agar at one point at a certain time. To ensure that the finger moves over the entire surface it shall be regularly monitored using the technique below. The resulting documentation is a quality record and shall be retained.
Prepare an assemblage, using the steel rings, consisting of one sheet of white paper, one sheet of carbon paper and one sheet of HD polyethylene film. Put a bottom part of a 14 cm Petri dish upside down on the rotating disk and the assemblage over it as described in A.5.3. Apply the finger to the materials and run the apparatus for 15 minutes. Extract the white paper and ensure that the finger has left an even contact pattern over the whole surface of the plate.

A.5.3 Procedure

A.5.3.1 Specimen preparation

Adjust the weight on the lever so that the force from the finger on the agar plate is (3 ± 0,02) N.

Place agar plate 1 on the turntable.

To standardize the material stretching force, use the following technique. Use a circular weight consisting of an outer and an inner ring (total weight (800 ± 1) g, see figures A.3 and A.4).

Put the inner ring and a cylindrical body approx. 9 cm in diameter and 4 cm high in its centre onto a horizontal sterile working surface. Use suitable means such as double sided adhesive tape on the outside of the ring to increase friction.

Put a test specimen on the ring and the donor, contaminated side down, removed from the paper and a piece of HD polyethylene on top of it. Now push the outer ring down firmly so that the materials are securely held between the two rings.

A.5.3.2 Test sequence (specimen 1)

The assemblage can now be lifted with the materials slightly slack and placed on the lidless first agar plate with the steel ring hanging freely outside the rotating disk. Apply the finger to

the donor material just inside the brim and in such a way that the test specimen comes into contact with the agar surface. Start running the test as described with a finger force of 3 N and for 15 minutes.

Remove the steel ring with the donor-test piece combination immediately when the 15 minute period has elapsed.

Remove plate 1 from the rotating disk and put the lid on it. Immediately put plate 2 on the rotating disk and the ring with the materials on it.

Repeat the above for plates 2 to 5, using the same material assemblage.

Finally remove and discard the donor, turn the test specimen upside down, cover with the HD polyethylene film and run the sixth plate for 15 minutes.

If liquid has accumulated on the agar surface dry the plate(s) in a clean bench and incubate the agar plates (1 to 6) with their lids on in a thermostat at (36 ± 1) °C for 48 h.

Count the colonies of S. aureus on each plate. Disregard the count in the area of 15 mm radius around the center of the plate. The plate count shall not exceed 1000. If a colony count exceeds 1000, a new S. Aureus suspension with a lower concentration (but still in the fixed range) shall be made and that replicate shall be repeated.

A.5.3.3 Remaining specimens

Run the remaining 4 test specimens in the same way as described in A.5.3.1 and A.5.3.2. Use a freshly prepared donor with each test specimen.

A.6 Calculation of results

Calculate the expected plate for penetration (EPP) as follows,:

$$EPP = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$$

where:

$CUM1 = X1/T$

$CUM2 = (X2 + X1)/T$

$CUM3 = (X3 + X2 + X1)/T$

$CUM4 = (X4 + X3 + X2 + X1)/T$

$CUM5 = (X5 + X4 + X3 + X2 + X1)/T$

$T = Z + X1 + X2 + X3 + X4 + X5$

X1, X2, X3, X4 and X5 are the numbers of colonies on the five plates from one of five specimens.

Z is the plate count from the inverted test specimen.

A.7 Test report

The test report shall include the following:

1) reference to this European Standard and this annex;

2) reference to calibrations, if any;

3) test conditions i. e. temperature and humidity;

4) distance from agar surface to brim of Petri dish;

5) identification of material tested;

6) statement that the donor material corresponds with A.3.3;

7) colony count results from the six test plates of each of the 5 test specimens;

8) viable counts of the S. aureus suspensions used;

9) calculated EPP characteristic, mean and standard deviation over the five test specimens.

Annex ZA
(informative)
Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a Mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 89/686/EEC.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard given in Table ZA.1 are likely to support requirements of Directive 89/686/EEC, Annex II.

Table ZA.1 — Comparison between EU Directive 89/686/EEC and this European Standard

Basic requirement (EU Directive 89/686/EEC, Annex II)	**Clause(s) of this standard**
1.1.2.2 Levels and classes of protection	4.1.4
1.3.1 Adaptation to user morphology	4.3
1.3.2 Lightness and design strength	4.1.2
1.4 Information supplied by the manufacturer	6
2.12 PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety	5
3.10.2 Protection against dangerous substances and infective agents	4.3, 4.1.4

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Bibliografi

[1] Ransjö U, Hambraeus A: An instrument for measuring the bacterial penetration through fabrics used for barrier clothing. Journal of Hygiene (1979) 82:361-368.

[2] Whyte W, Hambraeus A, Laurell G, Hoborn J: The relative importance of routes and sources of wound contamination during general surgery. I. Non-airborne. Journal of Hospital Infection (1991) 18:93-107.

[3] Werner HP, Hoborn J, Schön K, Petri B: Influence of drape permeability on wound contamination during mastectomy. European Journal of Surgery (1991) 157:379-383.

[4] Hoborn J: Theatre Drapes and Gowns – How to Determine Wet Bacterial Barrier Properties. HygMed (2000) 25:79-83.

[5] Hoborn J: How to Determine Bacterial Barrier Properties – Part II: Further improvements. HygMed.

Informasi pendukung terkait perumus standar

[1] KomiteTeknis
Komite Teknis 13-09 Biosafety and Biosecurity

[2] Susunan Keanggotaan KomiteTeknis

Ketua	:	Sunarya	- The Spring Institute
Sekretaris	:	Agus Purnawarman	- Badan Standardisasi Nasional
Anggota	:	1. Diah Iskandriati	- Pusat Studi Satwa Primata, Lembaga Penelitian dan Pengabdian kepada Masyarakat, IPB University
	:	2. Syafril Daulay	- Komisi Ahli, Badan Karantina Pertanian Kementerian Pertanian
	:	3. Ni Ketut Susilarini	- Pusat Penelitian dan Pengembangan Biomedis dan Teknologi Dasar Kesehatan, Badan Litbangkes, Kementerian Kesehatan
	:	4. Indrawati Sendow	- Balai Besar Penelitian Veteriner
	:	5. Lilyana Budihardjo	- PT.Gaia Science Indonesia
	:	6. Rika R.Sjoekri	- CV.Noesis
	:	7. Arnold Sudharyanto	- PT.Trisakti Mekarmandiri
	:	8. Wanny Basuki	- World BioHazTech Pte. Ltd.
	:	9. Ni Made Ria Isriyanthi	- Subdit Pengawasan Obat Hewan, Direktorat Kesehatan Hewan Direktorat Peternakan dan Kesehatan Hewan. Kementerian Pertanian
	:	10. Aroem Naroeni	- Pusat Riset Virologi (PRVKP), Fakultas Kedokteran Universitas Indonesia
	:	11. Nuryani Zainuddin	- Balai Besar Karantina Pertanian Soekarno Hatta, Badan Karantina Pertanian, Kementerian Pertanian

[3] Konseptor
Gugus Kerja Komtek 13-09

[4] Sekretariat Pengelola KomiteTeknis
Direktorat Pengembangan Standar Agro, Kimia, Kesehatan dan Halal
Badan Standardisasi Nasional